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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NGUYEN, DAVE TRONG	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 01/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/845,080	NAIMARK ET AL.	
	Examiner	Art Unit	
	Dave T Nguyen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-15,17,37 and 40-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-3,7-15,17,37 and 40-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 11, 2003 has been entered.

Claims 1, 40, and 42 have been amended by the amendment filed August 11, 2003.

Claims 4-5 directed to non-elected species have been withdrawn from further consideration by the Examiner. The examiner acknowledges that claim 9 is drawn to the elected species and thus will be included in the examination.

Claims 1-3, 7-15, 17, 37, 40-42, to which the following grounds of rejection are applicable, are pending.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United

States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 7-15, 17, 37, 40-42 readable on:

A method of using suitable polymer microparticles to protect a pharmaceutical effectiveness of a pharmaceutically active agent, comprising:

Providing a pharmaceutically acceptable suspension comprising a pharmaceutically active agent, *e.g.,* drugs, protein, DNA, plasmids, or any biologically active agents known in the prior art, commingled with previously formed polymer microparticles, *e.g.,* polystyrene based polymer,

and exposing and contacting said pharmaceutically acceptable suspension to an endoluminal drug delivery catheter comprising a stainless steel based metal,

are rejected under 35 USC 102(e) as being anticipated by Pinchuck *et al.* (US 2002/0107330), or in the alternative under 35 USC 103(a), as being unpatentable over Pinchuck *et al.* (US 2002/0107330) taken with Rosenman (US 2003/0073972).

Pinchuk *et al.* teach a medical device, *e.g.,* vascular catheters, guide wires, stents, stent grafts, and a coating over at least a portion or the entirety of the medical device, the coating comprising a biocompatible block copolymer which further comprises polystyrene based polymers, *e.g.,* page 1, paragraphs 0010-0016, page 2, par. 0019-0022, column 2, p. 2, par. 0037, p. 3, par 0040. The teaching of a suspension comprising the block copolymers and a therapeutic agent, wherein the copolymers and therapeutic agents are both present or commingled in a buffered solution before being exposed to a medical device, is clearly taught on page 9, paragraph 0190, and paragraph 0196. Pinchuck also teaches that the microparticles are provided in an amount of an exemplified 1 wt%, *e.g.,* p. 4, par. 0059, page 8, pars 0176-0178, page 11, example 2. The dimensions of the polymeric coating of from about 0.5 microns to 50 microns are disclosed on page 9, par. 0195. Metallic based medical devices are disclosed on page 8, par. 0180. Adenoviral vectors as therapeutic agents are disclosed on page 5, paragraph 0089.

With respect to the limitation, which indicates that the previously formed microparticles are combined with a therapeutic agent, Pinchuck teaches that the formed

block-copolymer can be used to combined with a drug prior to being used a delivery catheter, page 4, par. 0059, page 8, par. 0186.

With respect to the limitation, which indicates that the catheter delivery device is for endoluminal delivery, given that the drug delivery catheter of Pinchuk can be implanted in any target tissue site *in vivo,* page 1, par. 0013, the catheter of Pinchuk is an endoluminal drug delivery device.

To the extent that the claims may read on the use of a growth factor or angiogenic drug encapsulated microspheres intended for treating a target site residing in a myocardium, Rosenman teaches that it is well recognized in the prior art to employ a suspension comprising a previously formed microsphere and a drug as a controlled release structure, and that the structure or composition can be used in his improved endoluminal drug delivery catheter for delivering a drug of choice to a target site within the heart (par. 0011-0012, 0049, 0061, 0061-0063, 0065).

As such, it would have been obvious for a skilled artisan to incorporate the block-copolymer/drug containing suspension in the metallic based catheter of Rosenman so as to enhance the delivery of a drug targeted for the heart or tumor in a treated subject. One would have been motivated to do so because Rosenman teaches that his catheter if employed is suitable for delivery of small controlled release structures such as microparticles to a depth of the myocardium while lowering the risk of embolic events.

Absent evidence to the contrary and give all of the limitations are met by the disclosure of Pinchuck *et al.,* the claims are clearly anticipated by, or in the alternative, rendered *prima facie* obvious by Pinchuck *et al.* taken with Rosenman.

Claims 1, 2, 7-15, 17, 37, 40-42 readable on:

A method of using suitable polymer microparticles to protect a pharmaceutical effectiveness of a pharmaceutically active agent, comprising:

Providing a pharmaceutically acceptable suspension comprising a pharmaceutically active agent, *e.g.,* drugs, protein, DNA, plasmids, or any biologically active agents known in the prior art, commingled with suitable polymer microparticles, *e.g.,* polystyrene based polymer, and a metal compound, *e.g.,* any metal compound including those metal compounds that form basic components of a metallic medical delivery device,

wherein said polymer microparticles result in a pharmaceutical effectiveness of the pharmaceutically active agent in the absence of the microparticles,

are rejected under 35 USC 103(a) as being unpatentable over either Palasis (US 6,638,259) or Barry (US Pat No. 6,663,606) taken with Pinchuk or Rosenman.

Both Palasis and Barry teaches a method of employing a polymer such as a polystyrene based polymer or latex bead based polymer coated endoluminal drug delivery catheter for delivering drugs such as growth factors, angiogenic proteins, viral vectors coding for angiogenic proteins to a target site within an organ or tissue such as the heart, *e.g.,* column 3 through column 4 column 5 bridging column 6 (Palasis); column 3 through column 4 column 5 bridging column 6, columns 7 and 8 (Barry).

Palasis and Barry do not teach that the drugs are combined with a previously formed polymer so as to formulate a controlled release drug encapsulated microparticle, which are for use in the drug delivery catheter.

However, the concept of employing a controlled release drug encapsulated microparticle, wherein the previously formed microparticles are combined with a drug of choice in a suspension, in a drug delivery catheter is well-known in the prior art, as exemplified in both Pinchuk and Rosenman. As such, both Pinchuk and Rosenman are applied here as indicated above. Also, the making of microparticle/drug containing suspension with a suitable percent weight of the microparticles relative to that the drug is well known in the prior art of record, and thus, would have been minor modifications to a skilled artisan.

In view of the teachings provided by the combined cited references as a whole, it would have been obvious for one of ordinary skill in the art to further incorporate a controlled release drug encapsulated microparticle, wherein the previously formed microparticles are combined with a drug of choice in a suspension, in the medical drug delivery catheter of both Palasis and Barry. One would have been motivated to do so because the combined cited references teach the controlled release structures once coated in the catheter would prolong the release and/or activity of the target drug at the target site.

Thus, the claimed invention as a whole was *prima facie* obvious.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 7-15, 17, 37, 40-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of either Palasis (US 6,638,259) or Barry II (US Pat No. 6,663,606), taken with Pinchuk or Rosenman.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Both claims Palasis and Barry claim a polystyrene based polymer or latex bead based polymer coated endoluminal drug delivery catheter for delivering a pharmaceutical active material such as protein drugs or viral vectors coding for the proteins to a target site within an organ or tissue such as the heart, *e.g.,* column 3 through column 4 column 5 bridging column 6 (Palasis); column 3 through column 4 column 5 bridging column 6, columns 7 and 8 (Barry).

Palasis and Barry do not teach that the pharmaceutically active material comprises a drug encapsulated microparticle, wherein drugs are combined with a previously formed polymers so as to formulate a controlled release drug encapsulated microparticle, which are for use in the drug delivery catheter.

However, the concept of employing a controlled release drug encapsulated microparticle, wherein the previously formed microparticles are combined with a drug of choice in a suspension, in a drug delivery catheter is well-known in the prior art, as exemplified in both Pinchuk and Rosenman. As such, both Pinchuk and Rosenman are applied here as indicated above. Also, the making of microparticle/drug containing suspension with a suitable percent weight of the microparticles relative to that the drug is well known in the prior art of record, and thus, would have been minor modifications to a skilled artisan.

In view of the teachings provided by the combined cited references as a whole, it would have been obvious for one of ordinary skill in the art to further incorporate a controlled release drug encapsulated microparticle, wherein the previously formed microparticles are combined with a drug of choice in a suspension, in the medical drug delivery catheter of both Palasis and Barry. One would have been motivated to do so because the combined cited references teach the controlled release structures once coated in the catheter would prolong the release and/or activity of the target drug at the target site.

Thus, the patent claims and the examined claims are obvious variants.

Applicant's response (pages 5-7) has been considered but is moot in view of the new grounds of the rejection.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051.**

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Please note that the examiner is expected to move to a new US PTO office building located in Alexandria on January 12, 2004. The examiner office phone number at the new building is **571-272-0731.**

Dave Nguyen
Primary Examiner
Art Unit: 1632

DAVE T. NGUYEN
PRIMARY EXAMINER